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43850

7590

09/02/2009

MORGAN, LEWIS & BOCKIUS LLP (SF)
One Market, Spear Street Tower, Suite 2800
San Francisco, CA 94105

EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 09/02/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,972	12/05/2005	Shawn DeFrees	101961-01-5083-US01	2406

TITLE OF INVENTION: ERYTHROPOIETIN: REMODELING AND GLYCOCONJUGATION OF ERYTHROPOIETIN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	12/02/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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43850 7590 09/02/2009

MORGAN, LEWIS & BOCKIUS LLP (SF)
One Market, Spear Street Tower, Suite 2800
San Francisco, CA 94105

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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,972	12/05/2005	Shawn DeFrees	101961-01-5083-US01	2406

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nonprovisional	YES	\$755	\$300	\$0	\$1055	12/02/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
HEARD, THOMAS SWEENEY	1654	514-008000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.111. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/530,972	12/05/2005	Shawn DeFrees	101961-01-5083-US01	2406
43850	7590	09/02/2009	EXAMINER	
HEARD, THOMAS SWEENEY				
ART UNIT			PAPER NUMBER	

1654

DATE MAILED: 09/02/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 145 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 145 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/530,972

Applicant(s)

DEFREES ET AL.

Examiner

THOMAS S. HEARD

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Examiner's Amendment proposal, August 12, 2009.
2. ☒ The allowed claim(s) is/are 12-18, 23-69, 72-76 and 78-96.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 05/13/2009
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

DETAILED ACTION

The Election Restriction requirement made on 12/07/2007 is hereby withdrawn.

Terminal Disclaimer

The terminal disclaimers filed on 4/22/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 7,138,371, 7,405,198, and 11/144,223, and has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ada Wong, Reg. No. 55,740, on August 13, 2009.

The application has been amended as follows:

The following claims replace all previously submitted claims:

1-11. (Cancelled)

12. (Previously presented) A glycoPEGylated EPO peptide comprising an EPO peptide and at least one glycan and at least one poly(ethylene glycol) molecule covalently attached to said glycan, wherein said glycoPEGylated EPO peptide is made by a method

comprising: adding said poly(ethylene glycol) molecule to said EPO peptide using a glycosyltransferase.

13. (Original) The glycoPEGylated EPO peptide of claim 12, comprising at least one mono-antennary glycan.

14. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein each of said at least one glycan is N-linked and mono-antennary.

15. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein each of said at least one glycan is N-linked and at least one of said glycans comprise said poly(ethylene glycol).

16. (Original) The glycoPEGylated EPO peptide of claim 15, wherein more than one of said glycans comprises said poly(ethylene glycol).

17. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein each of said at least one glycan is N-linked and all of said glycans comprise said poly(ethylene glycol).

18. (Original) The glycoPEGylated EPO peptide of claim 12, comprising at least three mono-antennary glycans having said poly(ethylene glycol) covalently attached thereto.

19-22. (Cancelled)

23. (Original) The glycoPEGylated EPO peptide of claim 12 wherein said poly(ethylene glycol) is linked to at least one sugar moiety selected from the group consisting of fucose (Fuc), N-acetylglucosamine (GlcNAc), galactose (Gal) and a sialic acid (SA).

24. (Original) The glycoPEGylated EPO peptide of claim 23, wherein said sialic acid is N-acetylneuraminic acid.

25. (Original) The glycoPEGylated EPO peptide of claim 12, wherein said EPO peptide does not comprise an O-linked glycan.

26. (Original) The glycoPEGylated EPO peptide of claim 12 wherein said EPO peptide comprises at least one O-linked glycan.

27. (Previously presented) The glycoPEGylated EPO peptide of claim 26, wherein said O-linked glycan comprises said poly(ethylene glycol) covalently attached thereto.

28. (Original) The glycoPEGylated EPO peptide of claim 27, wherein said EPO peptide is recombinantly expressed in a cell.

29. (Original) The glycoPEGylated EPO peptide of claim 28, wherein said cell is selected from the group consisting of an insect cell, a fungal cell and a mammalian cell.

30. (Cancelled)

31. (Original) The glycoPEGylated EPO peptide of claim 29, wherein said cell is an insect cell.

32. (Original) The glycoPEGylated EPO peptide of claim 29, wherein said cell is a yeast cell.

33. (Original) The glycoPEGylated EPO peptide of claim 29, wherein said cell is a mammalian cell.

34. (Original) The glycoPEGylated EPO peptide of claim 33, wherein said mammalian cell is a CHO cell.

35. (Original) The glycoPEGylated EPO peptide of claim 12, wherein said poly(ethylene glycol) has a molecular weight selected from the group consisting of about 1 kDa, 2 kDa, 5 kDa, 10 kDa, 20 kDa, 30 kDa and 40 kDa.

36. (Original) The glycoPEGylated EPO peptide of claim 35, wherein said poly(ethylene glycol) has a molecular weight of 20 kDa.

37. (Original) The glycoPEGylated EPO peptide of claim 12, wherein said EPO peptide is selected from the group consisting of a naturally occurring EPO peptide and a mutated EPO peptide.

38. (Original) The glycoPEGylated EPO peptide of claim 37, wherein said mutated EPO peptide comprises the amino acid sequence of SEQ ID NO:73 having at least one mutation selected from the group consisting of Arg¹³⁹ to Ala¹³⁹, Arg¹⁴³ to Ala¹⁴³ and Lys¹⁵⁴ to Ala¹⁵⁴.

39. (Withdrawn) A method of making a glycoPEGylated EPO peptide, said method comprising the step of:

(a) contacting an EPO peptide with a mixture comprising a nucleotide sugar covalently linked to poly(ethylene glycol) and a glycosyltransferase under conditions sufficient to transfer said poly(ethylene glycol) to said EPO peptide.

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40. (Withdrawn) The method of claim 39, wherein the sugar of said nucleotide sugar is selected from the group consisting of fucose (Fuc), N-acetylglucosamine (GlcNAc), galactose (Gal) and a sialic acid (SA).

41. (Withdrawn) The method of claim 40, wherein said sialic acid is N-acetylneuraminic acid (NAN).

42. (Withdrawn) The method of claim 39, wherein said poly(ethylene glycol) has a molecular weight selected from the group consisting of about 1 kDa, 2 kDa, 5 kDa, 10 kDa, 20 kDa, 30 kDa and 40 kDa.

43. (Withdrawn) The method of claim 42, wherein said poly(ethylene glycol) has a molecular weight of 20 kDa.

44. (Withdrawn) The method of claim 39, wherein said EPO peptide is recombinantly expressed in a cell.

45. (Withdrawn) The method of claim 44, wherein said cell is selected from the group consisting of an insect cell, a fungal cell and a mammalian cell.

46. (Withdrawn) The method of claim 45, wherein said cell is an insect cell.

47. (Withdrawn) The method of claim 45, wherein said cell is a yeast cell.

48. (Withdrawn) The method of claim 45, wherein said cell is a mammalian cell.

49. (Withdrawn) The method of claim 48, wherein said mammalian cell is a CHO cell.

50. (Withdrawn) The method of claim 39, wherein said EPO peptide is selected from the group consisting of a naturally occurring EPO peptide and a mutated EPO peptide.

51. (Withdrawn) The method of claim 50, wherein said mature EPO peptide has the sequence of SEQ ID NO:73.

52. (Withdrawn) The method of claim 50, wherein said mutated EPO peptide comprises the amino acid sequence of SEQ ID NO: 73 having at least one mutation selected from the group consisting of Arg¹³⁹ to Ala¹³⁹, Arg¹⁴³ to Ala¹⁴³ and Lys¹⁵⁴ to Ala¹⁵⁴.

53. (Withdrawn) The method of claim 39, wherein before step (a):

(b) contacting said EPO peptide with a mixture comprising a nucleotide-N-acetylglucosamine (GlcNAc) molecule and an N-acetylglucosamine transferase (GnT) for which the nucleotide-GlcNAc is a substrate under conditions sufficient to form a bond between said GlcNAc and said EPO, wherein said GnT is selected from the group consisting of GnT I, GnT II, GnT III, GnT IV, GnT V and GnT VI.

54. (Withdrawn) The method of claim 53, wherein said mixture comprises one GnT selected from the group consisting of GnT I, GnT II, GnT IV, GnT V and GnT VI.

55. (Withdrawn) The method of claim 54, wherein said GnT is GnT I.

56. (Withdrawn) The method of claim 54, wherein said GnT is GnT II.

57. (Withdrawn) The method of claim 39, wherein said glycoPEGylated EPO peptide comprises at least one mono-antennary glycan.

58. (Withdrawn) The method of claim 39, wherein the sugar of said nucleotide sugar is galactose and said glycosyltransferase is galactosyl transferase I (GalT I).

59. (Withdrawn) The method of claim 53, wherein before step (a) but after step (b):

(c) contacting said EPO peptide with a mixture comprising a nucleotide galactose (Gal) and galactosyl transferase I (GalT I) under conditions sufficient to transfer galactose to said EPO peptide.

60. (Withdrawn) The method of claim 39, wherein in step (a), the sugar of said nucleotide sugar is sialic acid and said glycosyltransferase is a sialyltransferase.

61. (Withdrawn) The method of claim 60, wherein said sialic acid is N-acetylneuraminic acid (NAN).

62. (Withdrawn) The method of claim 60, wherein said sialyltransferase is selected from the group consisting of $\alpha(2,3)$ sialyltransferase, $\alpha(2,6)$ sialyltransferase and $(2,8)$ sialyltransferase.

63. (Original) A glycoPEGylated EPO peptide made by the method of claim 39.

64. (Previously presented) A glycoPEGylated EPO peptide, said EPO peptide comprising the sequence of SEQ ID NO:73 and further comprising an intact glycosyl linking group linking said EPO peptide and a PEG moiety of said glycoPEGylated EPO peptide.

65. (Original) A glycoPEGylated EPO peptide, said EPO peptide comprising the sequence of SEQ ID NO:73 and further comprising a mutation in said sequence.

66. (Withdrawn) A method of making a glycoPEGylated EPO peptide, said method comprising the steps of:

(a) contacting an EPO peptide with a mixture comprising a nucleotide sugar covalently linked to poly(ethylene glycol) and a glycosyltransferase under conditions sufficient to transfer said poly(ethylene glycol) to said EPO peptide, wherein said glycosyltransferase is a fucosyltransferase.

67. (Withdrawn) The method of claim 66, wherein said fucosyltransferase is selected from the group consisting of fucosyltransferase I, fucosyltransferase III, fucosyltransferase IV, fucosyltransferase V, fucosyltransferase VI and fucosyltransferase VII.

68. (Original) A glycoPEGylated EPO peptide made by the method of claim 66.

69. (Withdrawn) The method of claim 66, wherein said EPO peptide is expressed in a CHO cell.

70. (Canceled)

71. (Canceled)

72. (Withdrawn – currently amended) A method of providing an EPO peptide ~~erythropoietin therapy~~ to a mammal, said method comprising administering an effective amount of a glycoPEGylated EPO peptide comprising an EPO peptide and at least one glycan and at least one poly(ethylene glycol) molecule covalently attached to said glycan, wherein said poly(ethylene glycol) molecule is added to said EPO peptide using a glycosyltransferase, wherein said EPO peptide is administered in an amount effective to increase the hematocrit level in said mammal.

73. (Withdrawn) The method of claim 72, wherein said mammal is a human.

74. (Withdrawn – currently amended) A method of treating a mammal having anemia, said method comprising administering to said mammal a glycoPEGylated EPO peptide comprising an EPO peptide and at least one glycan and at least one poly(ethylene glycol) molecule covalently attached to said glycan, wherein said poly(ethylene glycol) molecule is added to said EPO peptide using a glycosyltransferase, wherein said EPO peptide is administered in an amount effective to increase the hematocrit level in said mammal.[.]

75. (Withdrawn) The method of claim 74, wherein said mammal is a human.

76. (Withdrawn) The method of claim 75, wherein said anemia is associated with chemotherapy.

77. (Cancelled)

78. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said at least one glycan is a biantennary glycan.

79. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said at least one glycan is a triantennary glycan.

80. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said at least one glycan is at least a triantennary glycan.

81. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said at least one glycan comprises at least two glycans selected from mono- and multiantennary glycans.

82. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said at least one glycan is selected from N-linked glycans and O-linked glycans.

83. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said at least one glycan is at least two glycans selected from N-linked and O-linked glycans.

84. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said EPO peptide has the sequence of SEQ ID NO:73.

85. (Previously presented) The glycoPEGylated EPO peptide of claim 12, wherein said method comprises the step of:

(a) contacting an EPO peptide with a mixture comprising a nucleotide sugar derivatized with poly(ethylene glycol) and a glycosyltransferase under conditions sufficient to transfer said poly(ethylene glycol) to said EPO peptide.

86. (Previously presented) The glycoPEGylated EPO peptide of claim 85, wherein said nucleotide sugar comprises a sugar moiety selected from the group consisting of fucose (Fuc), N-acetylglucosamine (GlcNAc), galactose (Gal) and sialic acid (SA).

87. (Previously presented) The glycoPEGylated EPO peptide of claim 86, wherein said sialic acid is N-acetylneuraminic acid (NAN).

88. (Previously presented) The glycoPEGylated EPO peptide of claim 85, wherein said method further comprises prior to step (a):

(b) contacting said EPO peptide with a mixture comprising a nucleotide-N-acetylglucosamine (GlcNAc) molecule and an N-acetylglucosamine transferase (GnT) for which the nucleotide-GlcNAc is a substrate under conditions sufficient to form a bond between said GlcNAc and said EPO, wherein said GnT is selected from the group consisting of GnT I, GnT II, GnT III, GnT IV, GnT V and GnT VI.

89. (Previously presented) The glycoPEGylated EPO peptide of claim 88, wherein said mixture comprises one GnT selected from the group consisting of GnT I, GnT II, GnT IV, GnT V and GnT VI.

90. (Previously presented) The glycoPEGylated EPO peptide of claim 89, wherein said GnT is GnT I.

91. (Previously presented) The glycoPEGylated EPO peptide of claim 89, wherein said GnT is GnT II.

92. (Previously presented) The glycoPEGylated EPO peptide of claim 85, wherein said sugar of said nucleotide sugar is galactose and said glycosyltransferase is galactosyl transferase I (GalT I).

93. (Previously presented) The glycoPEGylated EPO peptide of claim 85, further comprising prior to step (a) but after step (b):

(c) contacting said EPO peptide with a mixture comprising a nucleotide galactose (Gal) and galactosyl transferase I (GalT I) under conditions sufficient to transfer galactose to said EPO peptide.

94. (Previously presented) The glycoPEGylated EPO peptide of claim 85, wherein said nucleotide sugar of step (a) comprises sialic acid and said glycosyltransferase is a sialyltransferase.

95. (Previously presented) The glycoPEGylated EPO peptide of claim 94, wherein said sialic acid is N-acetylneuraminic acid (NAN).

96. (Previously presented) The glycoPEGylated EPO peptide of claim 94, wherein said sialyltransferase is selected from the group consisting of $\alpha(2,3)$ sialyltransferase, $\alpha(2,6)$ sialyltransferase and $(2,8)$ sialyltransferase.

Conclusion

Claims 12-18, 23-69, 72-76, 78-96 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS S. HEARD whose telephone number is (571)272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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